Digitally signed by Ceaicovschi Tudor
Date: 2021.07.08 11:14:35 EEST
Reason: Aprob
Location: Moldova

Anexa 12. Analizator biochimic, automat 100 teste, cu sistem de tip deschis

Descriere	Analizator biochimic, automat 100 teste, cu sistem de tip deschis. Cod 150200. Descriere Analizator semiautomat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezenţa anumitor substanţe şi estimează concentraţiile lor într-o probă de urină	
Parametrul	**Specificația solicitata**	**Specificatia tehnica oferita Selectra ProS (Elitech/Olanda)**
Sistem analitic	Automat, cu calculator integrat sau exterior (procesor, monitor, tastatura+mouse.	Automatizat, cu calculator integrat (procesor, monitor, tastatura+mouse).
Tip de lucru	continuu	Continuu
Tip sistem	deschis	deschis
	randoom acces	random acces
Capacitatea (teste/oră)	≥100 (teste fotomerice, fara modul ISE)	133 (teste fotomerice, fara modul ISE)
Posibilitatea efectuării analizelor urgente	da	Da
Tipul dispozitivului	staţionar	Da
Tip probă	Ser şi plasmă	Ser şi plasmă
	urină	urină
	sînge integru	sînge integru
	CSF (lichid cefalo-rahidian)	CSF (lichid cefalo-rahidian)
Tip diluare	automat	automatizată
Sistem de spălare	TOTAL automat (cuvă, ac, sistem de dozare)	Total automatizată (cuvă, ac, sistem de dozare)
Program control al calității	da	Da
Compartiment reactivi cu răcire	da	Da
Rotor cu răcire pentru mentinerea probelor	cu termostat la 37 grade C	Da
Cuvă pentru probe reutilizabil da, (indicați ciclurile posibile de reutilizare)	da	Da, 10 000 cicluri
Regimuri de măsurare:	Cinetic	Cinetic

		Mono și bi-cromatic	Mono si bi-cromatic
		Imunoturbidimetrc	Imunoturbidimetrc
		Controlul cantității de reagent rămas	Controlul cantitătii de reagent rămas
Semnalizare		Lipsa reagent si proba	Da
Sistemul de dozare:	Reagenții:utilizare a minim 2 metodici:	metodici: mono și bireagent	metodici: mono si bireagent
	Volumul reagentului programabil cu pasul 1 µl.	Da	Da
		cu sensor de obstacole	Dispune de sensor de obstacole
Alimentarea		220 V, 50 Hz	220 V, 50 Hz

CERTIFICATE

Number: 2145682

The management system of the organization(s) and locations mentioned on the addendum belonging to:

ELITechGroup S.p.A.

Corso Svizzera 185
10149 Torino
Italy

including the implementation meets the requirements of the standard:

ISO 9001:2015

Scope:
The research and development, manufacture, distribution and servicing off "in-vitro" diagnostic medical devices based on molecular biology methods.
The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods.

Certificate expiry date: 7 January 2023
Certificate effective date: 31 January 2020
Certified since: 1 October 2013

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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ADDENDUM

To certificate: 2145682

The management system of the organization(s) and/or location(s) of:

ELITechGroup S.p.A.

Corso Svizzera 185
10149 Torino
Italy

Certified organization(s) and/or locations:	Different scope
ELITechGroup S.p.A. Corso Italia 22 20122 Milano Italy	Registered office without operational responsibilities
ELITechGroup S.p.A. Corso Svizzera 185 10149 Torino Italy	The research and development, manufacture, distribution and servicing off "in-vitro" diagnostic medical devices based on molecular biology methods. The distribution and servicing of "in-vitro" diagnostic medical devices based on conventional methods

Addendum expiry date: 7 January 2023
Addendum effective date: 31 January 2020

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
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Lloyd's Register

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

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Clinical Systems

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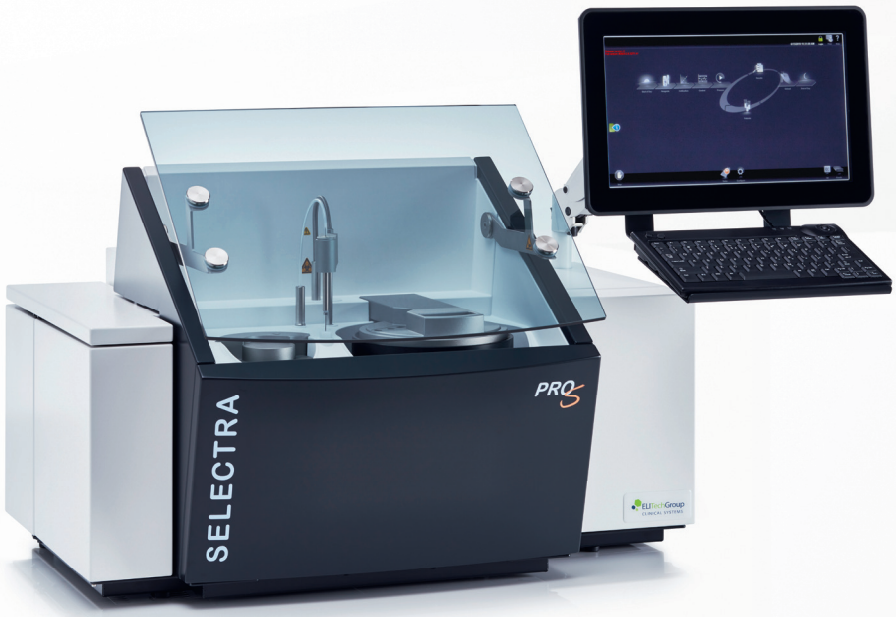
THE SMARTEST CHOICE FOR LABORATORIES LOOKING TO AUTOMATE



Cresce cum fide

Selectra Solutions

Clinical Systems

SPECIFICATIONS

THROUGHPUT
- Up to 133 tests/hour
- Up to 266 ISE tests/hour

REAGENT AND SAMPLE HANDLING
One rotor combining both sample and reagent positions.
- Inner rotor ring:
  - 30 refrigerated reagent positions for 10 mL, 25 mL and 50 mL reagent bottles
  - Cooled to 10°C +/-4°C at normal laboratory conditions
  - All reagent positions can be assigned as R1, R2 and R3
- Outer rotor ring:
  - 25 barcode readable positions
  - All positions fit 13x75 mm primary and secondary tubes and pediatric cups
  - All positions can be used for calibrators, controls, normal, pediatric and STAT samples

PIPETTING SYSTEM
- 1000 µL reagent syringe:
  - R 1 volume 110 - 400 µL
  - R 2 volume 0 - 180 µL
  - R 3 volume 0 - 180 µL
  - Programmable in 1 µL steps
- 100 µL sample syringe:
  - Sample volume 1 - 30 µL
  - Programmable in 0.1 µL steps
- Programmable dilution ratios: 1 : 5 up to 1 : 200 in one step increments with 3 possible diluents
- Pre-heated probe with level detection, collision protection and integrated mixer

CUVETTE ROTOR
- Cost effective, semi-disposable cuvette rotor with 48 cuvettes, path length 7 mm
- >10,000 tests per rotor
- Measuring temperature 37˚C, controlled by Peltier elements

LIGHT SOURCE
- Quartz-iodine lamp 12V-20W

WAVELENGTH RANGE
- 340 - 800 nm
- Optical unit with 8 position filter wheel
- Automatic wavelength selection
- 340, 405, 505, 546, 578, 620, 660, 700 nm standard installed
- Other wavelengths available on request

PHOTOMETRIC RANGE
- -0.1 to 3.0 Absorbance
- Resolution 0.001 Abs

ANALYTICAL MODES (SINGLE, DUAL AND TRIPLE REAGENT SYSTEM)
- Kinetic measurement with linearity check
- Mono- and bichromatic end point measurement with or without bichromatic reagent blank and/or sample blank correction
- Two point measurement; with or without slope blank
- Graphic plot of all measuring points
- Predilution, post-dilution and automatic reflex dilution as needed
- Non-linear calibration curves
- Prozone check for immunology tests
- Cut-off declaration
- Calculated tests

QUALITY CONTROL
- Up to 15 different controls can be defined, 3 per test
- Westgard rules
- Levey-Jennings plots
- Quality control statistics

WATER CONSUMPTION
- ~950 mL per hour max, continuous operation

STANDARDS AND REGULATIONS
- CE - IVDD
- USA FDA 510(k)
- CB
- UL

DIMENSIONS & WEIGHT
- 90 cm (36 in) x 75 cm (30 in) x 60 cm (24 in) (W x H x D)
- 75 kg (165 lbs)

INTERFACE
- State of the art Host-Query interface available
- Host: RS232 or Ethernet (TCP/IP) through LIS-2A protocol
- Hand held CCD barcode reader used for reagent identification and automated programming of assays, controls and calibrators

INSTALLATION CONDITIONS
- Temperature: 15 - 32 °C (59 - 90°F)
- Humidity: 15 - 85% RH
- Altitude: up to 2000 m
- Plumbing: no dedicated system water or drain required
- Electrical: Voltage: 100 - 240 Vac; Frequency: 50/60 Hz; Power (max): 400 VA

INTEGRATED PC
- Touch screen navigation
- Operating System: MS Windows™ Embedded

OPTIONS

ISE MODULE
- Patented Solid State Dry Electrode Technology
- Indirect measurement
- Dilution 1:14
- Measures Sodium, Potassium, Chloride and Bicarbonate

POSITIVE SAMPLE IDENTIFICATION
- Positive Sample Identification (PSID) via integrated barcode reader
- Reads all popular formats including Codes 39, 128, 11, 93, 4, CODABAR and Interleaved 2/5

PRINTER
- Printer supported by MS Windows™

PROACTIVE MAINTENANCE KIT
- Complete parts kit for annual preventive maintenance

Order code: 6003-500

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Clinical Systems

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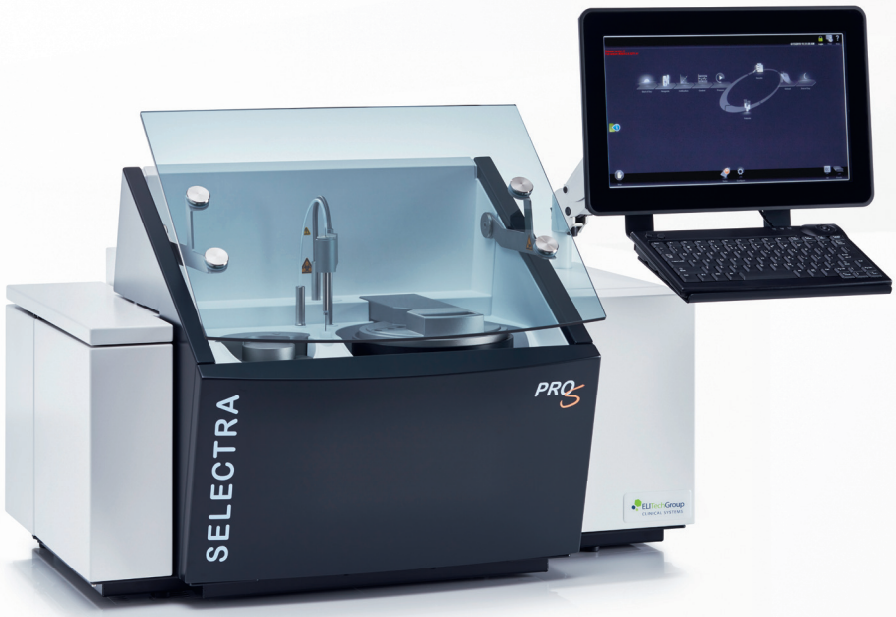

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Clinical Systems

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